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Regulatory
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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-160 12 VAC 5-165
Regulation title	Regulations for the Sanitary Control of the Picking, Packing and Marketing of Crab Meat for Human Consumption Regulations for the Repacking of Crab Meat for Human Consumption
Action title	Clarify certification requirements, remove standards that have no force of law, and modify repacking requirements.
Date this document prepared	1/15/2008

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

These regulations were adopted in 1965. The outcome of the adoption process ended with five general, noncontroversial rules adopted as “regulations”, and numerous specific details, some of which were controversial and adopted as “standards”. When the Virginia Administrative Code (VAC) was set up, the “standards” and the “regulations” were combined together and all listed as regulations. It is time to remove these “standards” (sections II through XVIII) from the VAC since they have no force of law.

A second concern within these regulations pertains to an original “regulation”, 12 VAC 5-160-20. This regulation stipulates that anyone cooking, picking and marketing crab meat must first obtain a Certificate of Inspection from the State Health Commissioner. This regulation needs to be reworded to make it clear that anyone that sells crab meat must be certified by the State Health Commissioner, whether they initially pick and pack the meat, or they simply repack the meat.

The crab meat repacking regulations, 12VAC5-165, pertain to the practice of transferring crab meat from one establishment’s container into the container of a different establishment. When these regulations were adopted in 2000, they were developed to address the situation where one dealer would purchase crab meat packed by one other certified crab meat establishment. Most crab meat shipped into the United States from foreign companies now originates from up to thirty or more different processing

facilities, even though it is shipped in one cargo container by one exporter to the US. The one-on-one relationship between the original picking plant and the Virginia crab meat establishment no longer exists in most instances, and several of the requirements that depended upon this relationship cannot be reliably met. We must develop new processes for assuring the safety of this meat.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Code of Virginia §28.2-800

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The elimination of sections II through XVIII of 12 VAC-160 is necessary because those sections were not adopted through the regulatory process that existed at the time, and are thus invalid as regulations.

Regulation 12 VAC 5-160-20 needs to be reworded to make the intent clear that all operations involving the packing of crab meat for sale requires certification by the State Health Commissioner.

Some of the provisions of 12 VAC 5-165 cannot be met by certified Virginia repacking establishments because of changes in the way that crab meat is being initially packed in foreign countries and shipped into the US. Alternative requirements that Virginia establishments can reasonably meet and that will address the existing risks must be developed.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

Sections II through XVIII, which were never adopted as regulations, are proposed for removal.

Regulation 12 VAC 5-160-20 is proposed to be reworded approximately as “Any person, firm or corporation operating an establishment for the purpose of marketing crab meat, which that person, firm or corporation has picked, packed or repacked, shall first obtain the approval of the State Health Commissioner in the form of a Certificate of Inspection.”

The Department will propose eliminating 12 VAC 5-165-90, which is a requirement for a repacker to obtain a record of shipping temperatures for imported crab meat. Such a temperature record is almost impossible to obtain given the magnitude of the current food shipping system. The Department will

propose that microbiological sampling results and organoleptic sensing be used to check for temperature abuse of the crab meat.

The Department proposes modifying 12 VAC 5-165-100.A , which addresses sampling requirements for imported crab meat to be repacked. When a repacker is importing crab meat from one source plant, then the original requirement for the first two shipments to be sampled, followed by a minimum of quarterly sampling, would remain as originally established. However, when a repacker uses crab meat shipped by one exporter, but which has been picked by more than one originating plant in the foreign country, then lot-by-lot sampling would be required.

The Department proposes modifying 12 VAC 5-165-100.B, which addresses organoleptic sensing. There is a lack of local capacity to train persons in organoleptic sensing to the level of being certified in seafood decomposition, which has made this regulation impractical. In its place, repacking establishments would organoleptically sense, to the best of the individual's capability, each container when opened and keep records attesting to this practice. Unsatisfactory containers would be discarded and a record kept of this process.

The Department proposes modifying 12 VAC 5-165-110, which addresses the verification of pasteurization of imported crab meat. Since crab meat is now being initially picked and packed by numerous facilities in foreign countries prior to being shipped by one exporter, obtaining letters from each facility, which state that the meat has been pasteurized, is at best an unreliable verification tool. Instead of requiring such letters, the Department will place the burden of assuring this process upon the repacker. Results of microbiological analyses on a lot-by-lot basis will help assure that a satisfactory heat treatment has been used.

The Department proposes evaluating 12 VAC 5-165-160, which forbids the blending of crab meat from more than one foreign processor. Compliance with this regulation would appear nearly impossible, since most of the imported crab meat has been compiled from many establishments before being exported from the foreign country. The original purpose of this regulation was to aid in trace-back efforts in the event of an illness. If this regulation is deleted and there is an outbreak of food-borne illness associated with a particular exporter, then a wider ban on repacking those imports might result.

The Department proposes evaluating 12 VAC 5-165-220.B, which requires that the lot number indicate the original source firm that picked the crab meat. Since a reliable indication of the establishment that picked the meat may be unrealistic, some other means of identifying lot numbers needs to be addressed.

The Department proposes evaluating 12 VAC 5-165-270, which details the particular records to be kept by the Virginia repacker. One of these records to be kept pertains to the source plant(s) for each lot; whether this requirement is realistic or not needs assessment.

Other sections of this regulation may be addressed during this process.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

The only viable option is to leave the regulations as they are currently written.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the *Code of Virginia*. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Bob Croonenberghs, 109 Governor Street, Suite 614, Richmond, Virginia 23219, (804)864-7477 (phone), (804)864-7481 (fax), bob.croonenberghs@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

In addition, the agency is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.}

A public hearing will be held.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The agency is using the participatory approach in the development of the proposal.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and

one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

- 1) The proposed modification of these regulations will neither strengthen nor erode the authority and rights of parents in the education, nurturing, and supervision of their children.
- 2) The proposed modification of these regulations will neither encourage nor discourage economic self-sufficiency, self-pride, nor the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents.
- 3) The proposed modification of these regulations will neither strengthen nor erode the marital commitment.
- 4) The proposed modification of these regulations will neither increase nor decrease disposable family income.

Periodic review – Public comment

If this NOIRA is not the result of a periodic review of the regulation, please delete this entire section.

If this NOIRA is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 36, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

Commenter	Comment	Agency response
No one	none	none

Parts of Regulation 12 VAC 5-160 are necessary for the protection of public health, safety and welfare. However, parts of it were not initially adopted as regulations and should be removed. Regulation 12 VAC 5-160-20 is not clearly written and needs a minor modification to make it clear.

Regulation 12 VAC-165 is necessary for the protection of public health, safety and welfare; and it is clearly written. However, since crab meat is now processed differently in foreign countries before being shipped into the US, adjustments in this regulation are needed to address these international changes.

Periodic review – Discussion

If this NOIRA is not the result of a periodic review of the regulation, please delete this entire section.

If this NOIRA is the result of a periodic review or if the periodic review is to be performed in combination with the NOIRA, please include a discussion of the agency’s consideration of: (1) the continued need for the rule; (2) the complexity of the regulation; (3) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency’s

determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

- (1) It is necessary to maintain most of these rules because the picking, packing and repacking of crab meat involves intensive hand contact, which provides the means for pathogenic organisms to be deposited on the cooked meat, and the meat is a ready-to-eat food.
- (2) These regulations are not particularly complex, they are detailed and specific to make them clear in their application.
- (3) These regulations do not overlap, duplicate or conflict with federal or state law or regulation.
- (4) These regulations were last evaluated in 2003-2004.